DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 16, 2015

BioMedical Enterprises, Incorporated
Mr. Joe Soward
Director, Quality Assurance and Regulatory Affairs
14785 Omicron Drive, Suite 205
San Antonio, Texas 78245

Re: K143023
Trade/Device Name: Nitinol Compression Plating System™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 16, 2014
Received: October 21, 2014

Dear Mr. Soward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143023

Device Name
Nitinol Compression Plating System™

Indications for Use *(Describe)*

• Fractures of various bones, including the clavicle, pelvis, scapula, long bones (humerus, radius, ulna, femur, tibia and fibula), and small bones such as metacarpals, metatarsals and phalanges.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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(510(k) Summary)

Product: Nitinol Compression Plating System™

Submitter Information

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San Antonio, Texas 78245
Telephone: (210) 677-0354
Fax: (210) 677-0355
Contact: Joe W. Soward

Date Prepared: October 16, 2014

Classification name: Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

Classification:	Class II
Product Code:	HRS
Common/Usual Name:	Bone Plate and Screws
Proprietary Name:	Nitinol Compression Plating system™

Intended Use:

The Nitinol Compression Plating System™ is indicated for:

- Fractures of various bones, including the clavicle, pelvis, scapula, long bones (humerus, radius, ulna, femur, tibia and fibula), and small bones such as metacarpals, metatarsals and phalanges.

Substantial Equivalence:

The Nitinol Compression Plating System™ is substantially equivalent to primary predicate GPC Bone Plates and Bone Screws cleared in K092493. The bundled clearance also included the DHS/DCS Plate System, the designs and indications of which we do not claim substantial equivalence. In addition, the BME Nitinol Compression Plating System™ is manufactured from many of the same materials and is substantially equivalent in potentiodynamic breakdown testing as cleared reference device BME Speed Triad™ K133844.

Device Description

The BME Nitinol Compression Plating System™ (NCP) consists of a sterile bone plate offered in various configurations (outlined below) and sterile titanium screws. The Nitinol bone plate is situated on two bones, across the fracture site, with titanium locking screws extending through the plate and cortex. The Nitinol bone plate is activated at room temperature upon release from a constraining instrument. In its final configuration, the plate actively provides continuous compression across the fusion site.

The NCP system contains plates and screws in the same shapes and sizes as those offered in the GPC system. The configurations of the BME system include Straight, T-shaped and X-shaped implants.

The main difference between the BME Nitinol Compression Plating System™ and the primary predicate, GPC Medical Bone Fixation Plates and Screw System™ is that the NCP plate component is made of Nitinol and provides active compression while the GPC plate is made of titanium alloy (Ti-6Al-4V) and does not provide active compression. The second difference is that the BME implants are offered sterile and for single use, while GPC Medical offers their products as non-sterile. BME Nitinol Compression Plating System™ is a fully sterilized kit comprised of the bone plate, titanium screws, sizing templates and instruments. The GPC Bone Plates and Bone Screws are offered non-sterile in reusable trays.

Performance Bench Testing:

BME conducted a series of tests to compare the submitted devices to the predicates. A summary of the testing is shown in Table 5-2. The test device is the representative worst-case condition for all configurations.

Table 5-2: Summary of Bench Testing

Description	Part Number	Predicate	Standard	Conclusion
Static Bend	NP-35S-5	GPC	ASTM F382(2008) e1	Substantially Equivalent to predicate.
Dynamic Bend	NP-35S-5	GPC	ASTM F382(2008) e1	Substantially Equivalent to predicate.
Post Fatigue Corrosion	NP-35S-5	NA	ASTM F2129-08	Substantially Equivalent to predicate.
Post Fatigue Nickel Leaching	NP-35S-5	GPC GPC Screws	None	Substantially Equivalent to predicate.
Corrosion	NP-35S-5	BME Triad	ASTM F2129-08	Substantially Equivalent to predicate.
Galvanic Corrosion	NP-35S-5	NA	ASTM F3044-14	Substantially Equivalent to predicate.

Details of the bench testing can be found in individual test reports included with this submittal. The full test reports describe the purpose of each test, apparatus and equipment used, protocol, results, statistical analyses if any, and conclusions. Based on the results of this comparison, the Nitinol Compression Plating system™ is as safe, effective and performs as well or better than the GPC and BME predicate devices outlined within this submission.